

Appln. No. 10/666,335
Amd. dated November 8, 2006
Reply to Office Action of August 8, 2006

REMARKS

The Office Action and the cited and applied reference have been carefully reviewed. No claim is allowed. Claims 20-23 presently appear, with claim 24 (which corresponds to previously appearing and constructively elected claim 18) being newly added, and define patentable subject matter warranting their allowance. No new issues are raised and no further consideration or search is necessitated by the amendments to the claims. Entry of the amendment, reconsideration and allowance are hereby respectfully solicited.

Claims 20-23 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is obviated by the amendment to claim 20 to recite "pharmaceutical composition for treating infertility" as appears to be suggested by the examiner.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 20 and 21 have been rejected under 35 U.S.C. §102(e) as being anticipated by Ekins, US Patent 5,432,099. This rejection is respectfully traversed.

Ekins is directed to the determination of multiple analytes in solution. In Example 2 cited by the examiner, a solution containing TNF and hCG in a microtiter plate is analyzed

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with antibodies to TNF and to hCG. Therefore, Ekins does not relate to a pharmaceutical composition. However, the examiner is taking the position that, because the specification does not provide a particular definition for a "pharmaceutical composition" and the claims do not have any additional limitations with respect to structure or function, the solution of Ekins anticipates the presently claimed pharmaceutical composition.

MPEP 2111.01(I) states:

This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. (emphasis added)

MPEP 2111.01(III) continues by elaborating that "plain meaning" refers to ordinary and customary meaning given to the term by those of ordinary skill in the art, stating with citations to Federal Circuit Court of Appeals decisions:

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention."
Phillips v. AWH Corp., 75 USPQ2d 1321 (Fed. Cir. 2005, en banc)

and "In the absence of an express intent to impart a novel meaning to the claim term, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."

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In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.

Clearly, if the specification does not provide a particular definition for a "pharmaceutical composition", the ordinary and customary meaning of "pharmaceutical" as applied to "composition" as gleaned from reference sources such as dictionaries is presumed. Applicants have made no express intent to impart a novel meaning to "pharmaceutical composition" and it is clear from the specification that the "pharmaceutical composition" is intended to treat infertility. Attached hereto is a copy of the relevant page from THE NEW OXFORD DICTIONARY OF ENGLISH, Oxford University Press, 1998, which provides the meaning of "pharmaceutical" as "of or relating to medicinal drugs" when used as an adjective and as "a compound manufactured for use as a medicinal drug" when used as a noun.

Claim 20 is also amended to recite "pharmaceutical composition for treating infertility" as appears to be suggested by examiner, which now provides a function to the "pharmaceutical composition". Ekins' disclosure of a solution of analytes including TNF and hCG in the presence of antibodies against TNF

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and hCG for use in a multiple analyte assay is not a "pharmaceutical composition" within the ordinary and customary meaning of "pharmaceutical composition" as would be immediately recognized and understood by those of ordinary skill in the art. Accordingly, Ekins does not and cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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